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ASPS Informed Consent Resources

Introduction

Informed consent requires more than a patient merely signing a form. Rather, informed consent is a process that considers several important factors, including a patient's needs and preferences, compliance with laws and regulations, and patient education. Utilizing the informed consent process helps the patient to participate fully in decisions about his or her care, treatment, and services. As a result, informed consent is necessary for the purposes of both education and risk disclosure to the patient.

Physicians are obligated to review the risks of surgery and potential treatment alternatives with their patients prior to performing any procedure. A patient's informed consent implies that, before the operation, the patient fully understands the benefits, potential outcomes, and the likelihood of any future treatment after undergoing the operation. It is important that this information is communicated in a clear, concise, and organized manner that a patient can understand. Informed consent documents are a great tool to capture and document that all vital information has been discussed with a patient prior to performing surgery. These documents can also be used as evidence in a malpractice case to prove that the patient was fully advised as to the relevant information regarding the applicable procedure prior to the surgical services.

There is no single answer as to how much information is legally required to be provided to a patient in order to obtain that patient's informed consent. For example, some states apply the "reasonable patient" standard, requiring the physician to impart the amount of information that a "reasonable" patient would need to make a decision about treatment. Other states, however, apply the "reasonable physician" standard, where the physician needs to provide only the information that a typical, appropriately trained physician would give under the same facts and circumstances. Practically speaking, although there is no one standard for the amount of information that a physician must provide to the patient in order to obtain the patient's informed consent, the fact remains that the information must be sufficient to allow the patient to exercise proper decision-making pertaining to his or her own body. That said, as with any legal issue, it is incumbent upon the physician to be aware of his or her own state's requirements.

Using Informed Consent in Your Practice

It is important to note that informed consent discussions are the responsibility of the physician and cannot be delegated to nurses or other office staff. The physician, not the hospital, is responsible for obtaining informed consent from the patient. Additionally, informed consent applies to all courses of treatment, and does not apply solely to surgical procedures.

A strong informed consent process involves not only having the patient sign all documents, but also having an open dialogue with your patient to review any areas of concern and provide time for them to ask

questions about the procedure, complications, risks, and benefits. This also gives the physician an opportunity to determine if the patient has realistic goals and expectations of what can be accomplished by the procedure.

It is recommended that each physician establish a routine so that each patient is informed to the same level of detail. It is helpful to see a patient multiple times before performing elective surgery to ensure that the patient does not make a rushed decision. At each visit, document your discussion about the procedure, its risks, your patient's questions, and your pre-operative instructions. It is important not to overlook the topic of drug therapy as well. Patients need to know about the effect of medications they will need to take, possible allergic reactions, and specific precautions.

You may find that during a consultation, an outline may help remind you of the important parts of a particular condition of proposed treatment. Using an outline may ensure that you are less likely to overlook important details that should be covered with each patient.

Who Can Give Consent?

A competent adult is the only one authorized to give consent for a procedure. In the case of a minor, consent may only be obtained from a parent or legal guardian. In an emergency situation, seek advice on consent-related issues from the hospital administration, especially if a patient refuses treatment. Be sure to document every effort you made to provide treatment.

Recommended Components of Informed Consent

Generally, in order to obtain a patient's informed consent, a patient needs the following information:

- Diagnosis or suspected diagnoses;
- Description of procedure(s) to be performed or proposed treatment plan;
- Outline of the most likely and most significant risks, benefits, complications, and alternative treatment options; and
- Risks of necessary medications, analgesics, antibiotics, and their side effects on driving and other daily activities.

Recommended Components of an Informed Consent Document

Typically, in addition to each of the above-referenced components, an informed consent document also provides the following information:

- Acknowledgement that an appropriate informed consent discussion took place;
- Statement that the procedure was explained to the patient or guardian in detail;
- Recognition that the patient was advised of the relevant risks, realistic alternatives, and expected outcomes for the procedure;

- Agreement that the patient was given a chance to ask questions, and that the patient's questions were fully answered;
- Name of the hospital where the procedure will take place;
- Names of ALL practitioners performing the procedure and, if more than one practitioner, the individual responsibilities for the surgical services;
- Name and signature of the patient, or if appropriate, legal guardian;
- Date and time that consent is obtained;
- Name and signature of any person who witnessed the consent; and
- Name and signature of the physician who explained the procedure to the patient or guardian.

Be sure to use the consent form that is specific to the procedure you will be performing. Also, it is important to note that more than one consent form may be required if multiple procedures are taking place during the same surgical session. Additional disclosure forms may be needed, especially in cases that involve the implantation of certain medical devices. Also, implant manufacturers may require additional documentation.

Special Issues

Problematic Patients

Medical liability lawsuits are not often about a physician's failure to perform the proper medical treatment. Instead, such lawsuits often involve poor communication and strained relationships. A strong physician-patient relationship may be critical for the purposes of avoiding medical-legal concerns, as epitomized by the physician's presence to fully explain the proposed course of treatment and answer the patient's pertinent questions.

If a physician identifies a patient with unreasonable expectations who may be seeking more than a surgical procedure can deliver, action can be taken to either further educate the patient or the physician may decline to provide treatment. The best communication usually occurs during the first two consultations. If you believe these meetings were strained or difficult, it may be best to decline to provide the patient with surgical services. While it may be difficult to turn problematic patients away, they may end up costing you more than you could have ever earned treating them.

"Informed Refusal"

A developing legal argument is that patients were not fully informed by a physician before deciding against a course of treatment. Therefore, if a patient might suffer adverse consequences by electing against a recommended treatment option, the physician should carefully document that the patient was fully advised as to the potential for those adverse consequences.

Smoking and Plastic Surgery

Plastic surgery places great emphasis on both surgical techniques and treatments that promote normal wound healing in order to produce a superior surgical outcome. It has been observed and reported within a variety of surgical scenarios that smokers have impaired capacity for wound repair and a propensity for skin necrosis.

Physicians should ask patients to disclose their smoking status during consultation. Having a patient disclose this information may offer protection if that patient willingly misrepresents his or her smoking status and then has a smoking-related healing issue regarding the wound after surgery. It is important that you document within your chart notes that you counseled a patient who smokes regarding the increased risk of potential complications due to smoking and surgery.

Clinical Investigations

Informed consent must be obtained before a patient can participate in any clinical investigation. The Institutional Review Board (IRB) must review clinical investigations involving the use of patients to obtain research data through an intervention or interaction with the individual, or to collect identifiable private information for the clinical investigation. An IRB ensures that proper steps are taken to protect the rights and well-being of participants in research studies. Many IRBs have developed templates that clinical investigators can obtain, which can provide assistance in writing informed consent documents to ensure that no required portions are left out.

Informed consent ensures that a participant in a clinical trial understands the information and has the opportunity to consider initial and ongoing participation. Information in these forms should include:

- An explanation of the purpose of research;
- Expected duration of the study;
- Procedures to be followed;
- Devices or drugs used in the clinical investigation;
- Whether before and after pictures of the participant are required and a statement authorizing the release of pictures;
- A description of any risks, foreseeable discomfort, and benefits a participant might receive;
- Disclosure of alternative procedures or treatments; and
- A statement describing any additional costs a participant may assume during the investigation.

It is also important to include statements that the participation is voluntary and that refusal to participate will not change the standard of care that will be provided to the patient.

Informed Consent Sample Forms

Risk management and informed consent issues have become an integral part of the practice of medicine and surgery. It is vitally important to a physician's practice to document informed consent in the medical record of every patient for whom they provide treatment. Unfortunately, there is no single pre-printed consent form that adequately meets the needs of all physicians; however, this gives the physician control over what risk disclosure information will go into the medical records in his or her office.

The sample forms that have been included in this resource are guides to assist you in developing your own forms that will reflect your individual needs, as well as the requirements of your state and your own malpractice insurance carrier. These sample consent documents are not intended to define or serve as the standard of medical care, and should not be considered all-inclusive in defining other methods of care and risks encountered. In that regard, please note that neither this document nor the sample forms are intended to provide legal advice. Rather, physicians should consult their attorneys with specific questions regarding informed consent.